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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/420,092	10/18/99	LUO Y	A-68287/DJB/

HM12/1201

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EXAMINER	
FLOOD, M	
ART UNIT	**PAPER NUMBER**
1651	12

DATE MAILED: 12/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/420,092	Luo et al.
Examiner	**Group Art Unit**
Michele Flood	1651

☒ Responsive to communication(s) filed on *Oct 18, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-9* is/are pending in the application.

Of the above, claim(s) *2-9* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *9*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground that it is unreasonable to divide an application which has 9 claims into 5 different groups. This is unpersuasive because the claims are drawn to five different inventions. In the instant case: the invention of Group I is directed to a method for screening a bioactive agent capable of binding to a cell cycle protein R0101 (Seq. ID No.: 2); the invention of Group II is directed to a method for screening for a bioactive agent capable of interfering with the binding of a cell cycle protein R0101 (Seq. ID No.: 2) and a PCNA protein; the invention of Group III is directed a method for screening for a bioactive agent capable of modulating the activity of cell cycle protein R0101 (Seq. ID No.: 2); the invention of Group IV is directed to an antibody; and, the invention of Group V is directed a method of diagnosing cancer. Groups I-III are directed to four different inventions that require different process steps and ingredients and they can be used in different applications. Group IV is directed to a product that is patentably distinct and separate. Finally, Group V is directed to a method, which does not require the method steps or the ingredients of the other claimed inventions. Furthermore, the search and burden are substantial and not limited or encompassed by the search for the composition. Applicant's election of Group I, claim 1, is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-9 are withdrawn from further consideration as claims drawn to non-elected inventions with traverse, as required under 37 CFR 1.142(b).

2. This application contains claims 2-9 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

4.

Claim Rejections - 35 USC § 101

Claim 1 is rejected under 35 U.S.C. § 101 because the claim is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant specification that the protein described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", " [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", " [i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claim is drawn to a protein of as yet undetermined function or biological significance. The claim is drawn to an isolated cell cycle protein R0101 encoding Seq. ID No.: 2. The instant specification discloses that the claimed amino acid sequence can be employed to screen bioactive agents, when the cell cycle protein R0101 is combined with a bioactive agent by determining the binding capacity of the bioactive agent to the said cell cycle protein R0101 (Seq. ID No.: 2). The specification discloses that such a screening assay can be employed to identify compounds, which act as modulators of cell cycle activity. The instant application discloses that there are a plurality of different modulators that promote, enhance or deter inhibitors of cell proliferation and that the identification of such cell cycle components and modulators is highly desirable for the therapeutic use thereof. The instant specification further discloses that there are a plurality of different mammalian proteins which are known to function as cell cycle proteins. However, neither the instant specification or the art of record identifies even a single disease or disorder that has been shown to be associated with cell cycle protein R0101, the claimed amino acid and the protein encoded thereby can not be employed in either a screening or diagnostic capacity. For example, the instant specification incorporates by reference the teachings of Nagase et al. (DNA Research, 1995, 2: 37-43) on page 2, lines 5-6, of the instant specification. However, there is absolutely no evidence of record or any line of reasoning that would support a conclusion that the protein of the instant invention is associated in any way with the plurality of causally unrelated cDNA sequences cited in the reference of Nagase et al. in Table 3. For instance, Applicant asserts that the instant R0101 (Seq. ID No.: 2) as a cell cycle protein without providing

any evidence or examples to support such a conclusion. Thus, Applicant's assertion appears to be purely speculative and wholly unsupported by any evidence of record. Since the prior art indicates a mere 14% amino acid sequence identity to a protein without an established function of the instantly claimed cell cycle protein R0101 encoding Seq. ID No.: 2, one of ordinary skill in the art would not reasonably extrapolate or conclude a common function between structurally dissimilar proteins. Neither the instant specification or the art of record identifies even a single disease or disorder that has been shown to be associated with cell cycle protein R0101 of the instant invention. Since the cell cycle protein R0101 of the instant invention has not been shown to be associated with a particular physiological process that an artisan would wish to manipulate for assaying bioactive agents for the identification of compounds which bind thereto, the claimed cell cycle protein R0101 can not be used to identify compounds which would have the clinical effect of modulating processes of the cell cycle or which would be ultimately employed in a diagnostic capacity and therapeutic use thereof. Until some actual and specific significance can be attributed to the protein identified in the specification as cell cycle protein R0101 (Seq. ID No.: 2), or the gene encoding it, the instant invention is incomplete. The protein encoded by a DNA of the instant invention is a compound known to be structurally analogous to proteins which are known in the art as cell cycle proteins. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of bioactive agents capable of binding to the said cell cycle protein R0101 is clearly to use it as the object of further research

which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for cell cycle protein R0101 then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant speculates a method for screening for a bioactive agent capable of binding to a cell cycle protein R0101, said method comprising: (a) combining a cell cycle protein R0101 (Seq. ID No.: 2) and a candidate bioactive agent; and (b) determining the binding of said candidate bioactive agent to said cell cycle protein R0101 (Seq. ID No.: 2). However, Applicant's assertion is not enabled because there is no way of determining whether the protein corresponding to (Seq.

ID No.: 2) corresponds to any known protein with known activity, but for which the sequence is unknown. Therefore, the broad concept of using a cell cycle protein with (Seq. ID No.: 2) in a screening assay for determining the binding of candidate bioactive agents to the cell cycle protein R0101 is clearly beyond the skill of one of ordinary skill in the art, requiring enormous burden and experimentation without a reasonable expectation of success. Speculations does not constitute enablement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

LEON B. LANKFORD, JR.
PRIMARY EXAMINER

mcf

November 27, 2000